

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)	MDL NO. 1456
THIS DOCUMENT RELATES TO:)	Civil Action No. 01-12257-PBS
<i>The City of New York, et al.</i>)	Subcategory Case No: 03-10643-PBS
v.)	Judge Patti B. Saris
<i>Abbott Laboratories, et al.</i>))

PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO BOEHRINGER INGELHEIM ROXANE, INC.

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit their Reply Statement of Undisputed Material Facts Applicable to Defendant Boehringer Ingelheim Roxane, Inc. f/k/a Roxane Laboratories, Inc., (hereinafter "Roxane") in support of their Motion for Partial Summary Judgment.

GENERAL RESPONSES

1. Plaintiffs' alleged undisputed material facts based on Average Wholesale Price ("AWP") are immaterial and irrelevant to this motion, limited as it is to issues relating to the FUL. As Defendants point out in their own motion for summary judgment, CMS officials could not recall ever having used an AWP as the basis for a FUL. See Local Rule 56.1 Stmt. of Undisputed Material Facts Supporting Defs.' Joint Mot. For Summary Judgment on Pls.' "FUL Fraud" Claims ("Defs.' 56.1 Stmt.") as ¶ 34, filed May 15, 2009 [Docket No. 6054].

PLAINTIFF'S REPLY:

Plaintiffs object to General Response No. 1 to the extent that it implies that in an alternative circumstance wherein, as Plaintiffs postulate in their motion, Defendants' reported AWP prices were real and actually a composite of generally and currently available wholesale

prices to the provider classes of trade, CMS officials *would* decline to use them according to the dictates of the FUL regulation, which speaks in terms of the lowest published price, without regard to whether that price is an AWP, a WAC, or some other published price. What CMS did to set FUL, or to decline to do so in the face of an entirely inflated and fraudulent array of published prices, without the knowledge and understanding that this was what it was actually facing at the time, is irrelevant to any matter at issue on this motion, and its implications are entirely disputed. *See Declaration of Susan E. Gaston, dated June 15, 2009 (“Gaston Decl.”) at ¶ 7, ¶ 10, ¶ 12 (Exhibit C to the Affidavit of Joanne M. Cicala in Opposition to Defendants’ Joint Motion for Summary Judgment on Plaintiffs’ “FUL Fraud” Claims (“Cicala Aff.”) [Dkt. No. 6144]).*

2. Roxane disputes Plaintiffs’ alleged undisputed material facts based on Wholesale Acquisition Cost (“WAC”) to the extent that Plaintiffs allege facts related to WAC that extend beyond early 1998, on the grounds that Roxane stopped reporting WACs for its multisource products in late 1997 or early 1998. Pls.’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19.

PLAINTIFFS’ REPLY:

Plaintiffs acknowledge that Roxane stopped reporting WAC to the pricing compendia for its multisource products in 1998. No assertion of material undisputed fact in this motion intentionally contradicts this acknowledgement.

3. Roxane further disputes Plaintiffs’ alleged undisputed material facts to the extent that they imply that the State of New York (“New York”) of the New York Department of Health (“NYDOH”), the entity responsible for reimbursing Medicaid providers in New York, did not have access to actual prices for the Roxane Subject Drugs. New York and the NYDOH had access to Average Manufacturer Prices (“AMPs”). See Exhibit A, 12/12/08 Roxane 30(b)(6) Deposition (Judy Waterer) (hereafter, “Ex. A, 12/12/08 Waterer Dep.”) at 170:10-22 (“[States] would have access to [AMPs], either directly if the government chose to share it with them under a confidentiality agreement or indirectly by

doing a simple calculation on the rebates they get every quarter from [Roxane].”). In fact, since 1991, New York has had access to AMPs through the Unit Rebate Amounts (“URAs”) provided to it on a quarterly basis through the federal Medicaid Rebate Program. 42 U.S.C. § 1396r-8(b)(3)(A) (1991).

PLAINTIFFS’ REPLY:

Plaintiffs object to General Response No. 3. Whether New York has meaningful access to AMP, which is in dispute, federal statutes prohibit its use in reimbursement, (*see* Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008) (MIPPA)) and require that AMPs be held confidentially (*see* 42 U.S.C. 1396r-8(b)(3)(D)). See also Gaston Decl. at ¶ 6. Moreover, AMPs are not published, confidential, and are neither WAC nor AWP. *See* Plaintiffs’ Memorandum of Law in Opposition to Defendants’ Joint Motion for Summary Judgment on Plaintiffs’ “FUL Fraud” Claims and in Further Support of Plaintiffs’ Motion for Partial Summary Judgment on Their § 145-B Claim, (“Plaintiffs’ Memo in Opp.”) [Dky. No. 6147] at pp. 7-8.

4. Roxane further disputes Plaintiff’s recitation of the purportedly undisputed facts to the extent that it implies that New York set reimbursement rates in the belief that they were based on the actual selling prices for the Roxane Subject Drugs. As set forth in Defendants’ summary judgment papers, NYDOH has long understood that “a pharmacy’s acquisition cost for a drug is likely to be lower than the prices quote[d] in third-party pricing compendia such as the Red Book or First DataBank.” See Defs.’ 56.1 Stmt. At ¶¶ 60-63 (Aff. Of Cesar A. Perales, at ¶2 & Ex. A). New York’s knowledge is further demonstrated by the fact that during the notice-and-comment period for the FUL in 1986, the New York Department of Social Services (the predecessor to NYDOH) commented on three proposed alternatives for establishing the FUL and specifically urged the Health Care Financing Administration (“HCFA”) not to base FUL on published prices because “the advertised price found in the Red Book or the Blue Book may not reflect the actual purchase prices.” *Id.* at ¶¶ 60-61.

PLAINTIFFS' REPLY:

Plaintiffs object to Roxane's General Response No. 4 because it is irrelevant and immaterial to any matter at issue on this motion. Defendants' insistent reference to the awareness that one or more persons in New York government agencies may have had that the Defendants' published prices were inaccurate does not rise to the level of knowledge of the true facts, approval, or participation in the fraud required in order to absolve them from liability under Section 145-b. Apart from the result that Roxane's assertions if they were true, and which are entirely disputed, do not rise to an effective government knowledge defense, neither causation nor deception are elements of Plaintiffs' Section 145-b claims. *See* Plaintiffs' Memo in Opp. at pp. 2-3, and 5-8.

ROXANE SPECIFIC FACTS

1. The Roxane Drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Roxane's Published AWPs and WACs for these Drugs and NDCs. The exhibit notes which NDCs are associated with packages sizes that set the FUL.

Roxane's Response to Statement No. 1: Roxane does not dispute that Exhibit A to Plaintiffs' Roxane-Specific Statement purports to (1) list the Roxane drugs and NDCs that Plaintiffs have examined in connection with their motion, (2) set forth Roxane's published AWPs and WACs for these drugs and NDCs, and (3) note which NDCs are associated with the package sizes that set the FUL. Roxane disputes the data set forth in Exhibit A to the extent it is not properly supported by evidence in the record. Plaintiffs have cited no evidentiary basis for the data set forth in Exhibit A, as is required by Local Rule 56.1. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass 2006) (disregarding "purported statement of 'fact' not properly supported by citations to the record" in summary judgment pleadings).

Plaintiffs' Reply to Statement #1:

Roxane's dispute as to the data in Exhibit A not being properly supported by evidence in the record is baseless. Plaintiffs properly cited Roxane as the source of the Roxane AMP data and the First Databank NDDF data file (Alabama Production, FDB-AWP 030785 – 030795) as

the source of all other data (*see Exhibit A at 3*), which is the same source cited by Dr. Addanki. *See Affidavit of Dr. Sumanth Addanki dated May 15, 2009 [Dkt. No. 6056] at Exhibit 2* (identifying “First DataBank (Alabama Production) Data and NDDF (National Drug Data File)™ Documentation Manual (Rev. April 2000)” as a Data source). *See also Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs’ motion for partial summary judgment at ¶2, [Dkt. No. 6236]* which is incorporated herein

Roxane disputes that Plaintiffs’ Exhibit is accurate and/or complete but offers no evidence in support as required by Rule 56.1. Roxane’s other objections concerning admissibility are likewise baseless and unsubstantiated. No further reply is required.

2. The specific Roxane drugs at issue are Albuterol .83 mg/ml Solution and Ranitidine 150 MG Tablet.

Roxane’s Response to Statement No. 2: Roxane does not dispute that Roxane’s Albuterol 0.83%mg solution and Ranitidine 150mg tablet are drugs at issue in Plaintiffs’ motion. Plaintiffs, however, have cited no evidentiary basis for this alleged fact, as is required by Local Rule 56.1. See O’Brien, 440 F. Supp. 2d at 5 .1.

Plaintiffs’ Reply to Statement #2:

Undisputed. No reply required.

3. Roxane has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. *See Answer and Affirmative Defenses of Boehringer Ingelheim Roxane Inc. to the Revised First Amended Consolidated Complaint (“Roxane Answer”) [Docket #4851] at ¶132.*

Roxane’s Response to Statement No. 3: Roxane does not dispute that Roxane has entered into and executed the federal Medicaid Rebate agreement with the Secretary of Health and Human Services on behalf of all States. This fact, however, is immaterial to Plaintiffs’ motion.

Plaintiffs’ Reply to Statement #3:

Undisputed. No reply required.

4. Roxane knew that eligibility for reimbursement by Medicaid was an important issue for its customers. See Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/9/07 Deposition Transcript (Exhibit B) at 41:1-10 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B)”).

Roxane’s Response to Statement No. 4: Roxane disputes that it “knew that eligibility for reimbursement by Medicaid was an important issue for its customers.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that she did not “believe [Roxane] could exist as a pharmaceutical company unless [it] agreed to participate in the [Medicaid drug] programs, because nobody would buy [its] drugs. So it’s pretty much required.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 41:6-10.

Plaintiffs’ Reply to Statement #4:

Statement #4 is not seriously disputed. If Roxane believes that it would cease to exist unless it agreed to Medicaid, then it must also know that eligibility for reimbursement by Medicaid is an important issue for its customers. In any event, the parties agree that Roxane thought that its participation in Medicaid was important to its continued survival as a business. No further reply is required.

5. At all times relevant hereto, Roxane reported and/or controlled its published WACs. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 70:3-15; Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/10/07 Deposition Transcript (Exhibit C) at 420:5-426:16; 446:20-447:3 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C)”; Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 5/11/07 Deposition Transcript (Exhibit D) at 662:13-673:13; 712-714:13 (hereinafter, “Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D)”). Roxane has only one WAC at any given time and reported the same WAC to all publishing compendia. See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 616:18-21; 650:13-23.

Roxane’s Response to Statement No. 5: Roxane disputes that “[a]t all times relevant hereto, Roxane reported and/or controlled its published WACs.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that “[w]hen a product launches and when there are changes made, it [the WAC] would be reported.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 70:11-15. Ms. Waterer further testified that “it

was not industry practice to report WAC on multisource products” and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls.’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19. Mr. Waterer testified that the decision to stop reporting WACs to pricing compendia was “just another thing [Roxane] had to do to be in line with normal generic practices.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 669:13-19. But Roxane could not control when the compendia stopped reporting Roxane’s WACs. *See Exhibit B, 5/9/07 Roxane 30(b)(6) Deposition (Judy Waterer) (hereinafter, “Ex. B, 5/9/07 Waterer Dep.”)* at 130:4 – 131:25; Pls.’ Ex. C, 5/10/07 Waterer Dep. at 421:21 – 422:17 (“They were continuing to report WAC prices that we had told them were no longer valid.”).

With respect to the second sentence of Alleged Fact No. 5, Roxane disputes that it “has only one WAC at any given time and reported the same WAC to all publishing compendia.” This alleged fact is not properly supported by the evidence in the record. *O’Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that wholesalers have the same WAC for any particular drug. Pls.’ Ex. D, 5/11/07 Waterer Dep. at 616:18-21. And Ms. Waterer further testified that each of Roxane’s databases had the same WAC for each drug, “unless there was a typo or it was a database that was no longer kept current.” Pls.’ Ex. D, 5/11/01 Waterer Dep. at 650:13-23.

Plaintiffs’ Reply to Statement #5:

The parties agree that Roxane reported WAC to the pricing compendia for its products until 1997 or 1998, when it stopped reporting WAC for its multisource products. The parties furthermore agree that Roxane had only one WAC for a given product at a time. The remainder of Roxane’s response is irrelevant, disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

6. Roxane reported AWP to the publishing compendia. *See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 68:14-25; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 446:10-19.*

Roxane’s Response to Statement No. 6: Roxane does not dispute that Roxane provided AWP to the publishing compendia. Alleged Fact No. 6, however, is immaterial to Plaintiffs’ motion because, as set forth in General Response No. 1 above, CMS did not consider AWPs in setting FULs. *See* Defs.’ 56.1 Stmt. at ¶ 34.

Plaintiffs’ Reply to Statement #6:

The parties agree that Roxane reported AWP to the publishing compendia. Roxane’s response that the Statement is immaterial is incorrect. While CMS may never have set a FUL on

AWPs, CMS considered AWPs in setting the FUL. *See* 42 CFR § 447.332(b); *see* Gaston, Sue (1/24/2008) 144:21-146:16, attached as Exhibit B to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts Related to Federal Upper Limits ("FULs") and Applicable to All Thirteen FUL Defendants (the "FUL Thirteen") [Dkt. No. 6060]; *see* Gaston, Sue (3/19/08) 458:1-459:7 (Corrected Ex. B to Affidavit of Joanne M. Cicala in Opposition to Defendants' Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims [Dkt. No. 6144]).

7. All published AWPs reflect what Roxane submitted to the publishing compendia. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 82:16-84:4; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 650:13-23.

Roxane's Response to Statement No. 7: Roxane disputes that "[a]ll published AWPs reflect what Roxane submitted to the publishing compendia." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane "would not want [third-party compendia] putting false and misleading information out there," but Roxane would only check the reported price when the compendia would send a request to Roxane for verification of a price. Pls.' Ex. B, 5/9/07 Waterer Dep. at 82:25-83:11 ("Q. But Roxane does nothing to monitor the published prices, correct? A. To the best of my knowledge, with the exception of the times when they have sent us items saying, Please verify this, [...] that is when we look at how they have our prices listed.").

More generally, as this Court knows from the *McKesson* case, no manufacturer "controlled" its AWPs. AWPs were published by the national pricing compendia, including specifically First DataBank, that unilaterally and over some manufacturers' objections raised AWPs for their products as a result of an agreement with McKesson and other wholesalers. The *McKesson* case makes plain that First DataBank did not function as the manufacturers' agent and the manufacturers did not "control" their AWPs or other published prices. *See, e.g., New England Carpenters Health Benefits Fund. v. First DataBank, Inc.*, 244 F.R.D. 79 (D. Mass. 2007).

And in any event, Alleged Fact No. 7 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶3 4.

Plaintiffs' Reply to Statement #7:

The parties agree that it was Roxane's intent that the pricing compendia publish its reported prices accurately, and that Roxane responded to the compendia's requests to verify and correct the prices that the pricing compendia were publishing. *See* Roxane 30(b)(6) (Waterer)

5/9/07 Dep. (Exhibit B) at 82:16-84:4; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 650:13-23. Roxane offers no evidence to support its dispute of Statement #7, which seems to be that “all” of the published prices were correct, but offers no proof of any which were published in error, other than to say that when errors were found, Roxane corrected them. Roxane acknowledges, in Statement #8, below, that “[t]he pricing compendia would occasionally send us a voluminous report and say, Please check this for accuracy. And we would go through and verify if their records matched our records. And if they didn’t, we’d cross it out and put in the correct price, as we knew it, and send it back and hope that they would adjust it.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 62:19-63:1.” This does not amount to a serious dispute of the Statement. Responding further, plaintiffs’ incorporate their reply to Statement #6 herein.

The remainder of Roxane’s response constitutes argument improper in a 56.1 statement and is irrelevant and disputed. It is also incorrect that the McKesson case cited suggests that Roxane, a generic drug company which dictates AWP to the pricing compendia, and does not rely on the pricing compendia to mark up its WAC, is not in control of its published prices. On the contrary. *McKesson* is a case about some 400+ brand drugs involved in a particular scheme by First DataBank and McKesson to usurp the brand manufacturers’ traditional control over the mark-up which would apply to their reported WAC prices to general a published AWP. If anything, *McKesson* shows that in the absence of an instance of racketeering, manufacturers, not pricing compendia, are traditionally and ultimately responsible for their published prices, and as such are in control of them, except to the extent that mistakes are made, which they then have the opportunity to, and do correct, as Roxane here admits. No further reply is required.

8. Roxane knew and controlled the AWPs and WACs for its drugs that were published by the national drug pricing compendia. Both Redbook and First Databank would send requests to Roxane to verify the accuracy of the AWPs and WACs for its drugs

and Roxane would respond with corrections if errors were found. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 62:7-63:17; 135:15-137:24; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 454:19-458:7; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 647:21-650:12.

Roxane's Response to Statement No. 8: Roxane disputes that it "knew and controlled the AWPs and WACs for its drugs that were published by the national drug pricing compendia." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane would only check the reported price when the compendia would send a request to Roxane for verification of a price. Pls.' Ex. B, 5/9/07 Waterer Dep. at 82:25-83:11 ("Q. But Roxane does nothing to monitor the published prices, correct? A. To the best of my knowledge, with the exception of the times when they have sent us items saying, Please verify this, [...] that is when we look at how they have our prices listed."). And, as stated more fully in Roxane's Response to Alleged Fact No. 7, no manufacturer "controlled" its AWPs. The McKesson case makes plain that manufacturers did not "control" their AWPs or other published prices. See, e.g., *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.D. 79 (D. Mass. 2007).

With respect to the second sentence of Alleged Fact No. 8, Roxane acknowledges that "[t]he pricing compendia would occasionally send us a voluminous report and say, Please check this for accuracy. And we would go through and verify if their records matched our records. And if they didn't, we'd cross it out and put in the correct price, as we knew it, and send it back and hope that they would adjust it." Pls.' Ex. B, 5/9/07 Waterer Dep. at 62:19-63:1.

But to the extent that Alleged Fact No. 8 addresses WACs, Ms. Waterer testified that "it was not industry practice to report WAC on multisource products" and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls.' Ex. C, 5/10/07 Waterer Dep. at 425:1-19. And, to the extent that Alleged Fact No. 8 addresses AWPs, it is immaterial to Plaintiffs' motion because, as set forth in General Response No., CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt. at ¶ 34.

Plaintiffs' Reply to Statement #8:

Roxane admits, in response to Statement #6, above, that it reported AWP to the pricing compendia. Roxane also admits in response to Statement #5, above, that when a product launched, or there was a change, it reported WAC to the pricing compendia until it stopped doing so in 1997 or 1998, and in response to Statement #8, that it verified the accuracy of the Roxane prices being published. Responding further, plaintiffs' incorporate their replies to Statements #5-7 herein.

The remainder of Roxane's response is improper argument, irrelevant and disputed. No further reply is required.

Roxane's Published AWPs and WACs had No Relationship to Actual Prices

9. For generic products Roxane was the first to launch, Roxane sets an AWP upon product launch at 10% below the brand AWP. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-23.

Roxane's Response to Alleged Fact No. 9: Roxane disputes that, in every instance, "for generic products Roxane was the first to launch, Roxane sets an AWP upon product launch at 10% below the brand AWP." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that when Roxane launches a new generic drug, the 'most common thing to do is take 10 percent of the brand's AWP at launch. There are instances when that does not occur.' Ex. A, 12/12/08 Waterer Dep. at 34:19-22. Alleged Fact No. 9, however, is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

Plaintiffs' Reply to Statement #9:

The parties agree that when Roxane's product was the first to launch, it most commonly set the product's AWP at 10% off the competing brand's AWP. Roxane offers no evidence of any occasion on which this did not occur. The remainder of Roxane's response is irrelevant and disputed. Responding further, plaintiffs' incorporate their reply to Statement #6 herein.

No further reply is required.

10. When Roxane launched a product into existing generic competition, it set the AWP at a level comparable to the AWPs of the competing products. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-23; Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 448:14-10; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 604:1-18.

Roxane's Response to Statement No. 10: Roxane does not dispute that, when it launched a product into an established market, Roxane typically "would have looked at what all of the competitors' AWPs were that were available and put [Roxane's] AWP so that it was in the same price range as theirs." Pls.' Ex. C, 5/10/07 Waterer Dep. at 449:2-10. Alleged Fact No.

10, however, is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

Plaintiffs' Reply to Statement #10:

Undisputed. Responding further, plaintiffs' incorporate their reply to Statement #6 herein.

11. Roxane's AWP has no connection whatsoever to actual prices charged by Roxane to any customers. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 70:16-71:9; 72:17-20; 79:19-80:13; 112:5-119:14; Waterer Deposition Exhibit No. 3 (Exhibit B); 123:5-129:15; Waterer Deposition Exhibit No. 4 (Exhibit B); Roxane 30(b)(6) (Waterer) 5/10/07 Dep. (Exhibit C) at 447:9-20; 454:7-18.

Roxane's Response to Statement No. 10: Roxane does not dispute that AWPs "do not reflect an actual price that anybody pays [Roxane] for [Roxane drugs]." Pls.' Ex. B, 5/9/07 Waterer Dep. at 79:23-25. In fact, nobody in the industry thought that AWPs bore a predictable relationship to market prices for generic drugs. Ex. A, 12/12/08 Waterer Dep. at 26:7-28:1 ("[W]e've never heard [AWP] described as anything else. In many, many, many years in the industry, [AWP] has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated average of prices in the marketplace."). And "the government would have every reason to know that [AWP] was not defined in the industry or in any general practice as some kind of actual average of wholesale prices." Ex. A, 12/12/08 Waterer Dep. at 138:14-139:11. This is because "[i]t would be irrational to think that anybody doing that reimbursement would think that that's the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was." Ex. A, 12/12/08 Waterer Dep. at 29:9-14.

But in any event, Alleged Fact No. 11 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1; CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

Plaintiffs' Reply to Statement #11:

Undisputed. Responding further, plaintiffs' incorporate their reply to Statement #6 herein. The remainder of Roxane's response is irrelevant, disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

12. Roxane's reported WACs are always higher than contract prices. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 150:3-151:11; Roxane 30(b)(6)

(Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-10; Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 7/24/07 Deposition Transcript (Exhibit E) at 753:10-756:7, (hereinafter, “Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E)”).

Roxane’s Response to Statement No. 12: Roxane does not dispute that Ms. Waterer agreed that “WAC prices are higher than contract prices.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 151:9-11. Ms. Waterer testified that Roxane “set WAC to be something that was, in general, higher than our highest contract price, so that there would still be a chargeback issued.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 150:12-22. And Ms. Waterer testified that “it was not industry practice to report WAC on multisource products” and that Roxane stopped reporting WACs for multisource products to pricing compendia in 1997 or 1998. Pls’ Ex. C, 5/10/07 Waterer Dep. at 425:1-19.

Plaintiffs’ Reply to Statement #12:

The Statement as written is undisputed. The remainder of Roxane’s response is irrelevant, disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

13. Most customers who purchase Roxane multisource products have contracts with Roxane. See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 552:18-554:17. All customers who have contracts with Roxane pay contract prices. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 52:12-17; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 581:23-582:7; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 761:22-762:8. Contract prices are below WAC even before any rebates, fees, credits are paid. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 72:21-73:8; 150:3-151:14; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-10; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 753:10-756:7. Contract prices are further reduced by subsequent rebates, fees and credits. See Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 788:17-792:1.

Roxane’s Response to Statement No. 13: Roxane acknowledges that most customers who purchase Roxane multisource products have contracts with Roxane. See Pls.’ Ex. D, 5/11/07 Waterer Dep. 553.4-13. With respect to the second sentence of Alleged Fact No. 13, Roxane disputes that “all customers who have contracts with Roxane pay contract prices.” This alleged fact is not properly supported by the evidence in the record. O’Brien, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that contract prices are “offer[ed] to pharmacy[ies], pharmacy chains, customers that are actually dispensing the product.” Pls.’ Ex. E, 7/24/07 Waterer Dep. at 762:5-8. Ms. Waterer also testified that contract prices are “discussed” and “agreed upon.” Pls.’ Ex. B, 5/9/07 Waterer Dep. at 52:12-17. And Ms. Waterer testified that “if there was a contract on an individual product, it would have sold at the contract price.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 582:5-7.

With respect to the third sentence of the Alleged Fact No. 13, Roxane disputes that “[c]ontract prices are below WAC even before any rebates, fees, credits are paid.” This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that, “[i]f the wholesaler does not sell [a drug] through a contract where we would honor a lower price, it will sell at WAC.” Pls' Ex. B, 5/9/07 Waterer Dep. at 73:3-5. Ms. Waterer also testified that Roxane “set WAC to be something that was, in general, higher than our highest contract price, so that there would still be a chargeback issued.” Pls.' Ex. B, 5/9/07 Waterer Dep. at 150:19-22. Plaintiffs offer no support for their assertion that contract prices are below WAC *even before* any rebates, fees, or credits paid. None of the evidence cited discusses whether rebates, fees, or other credits were ever included in the contract price. With respect to the fourth sentence of Alleged Fact No. 13, Roxane disputes that “[c]ontract prices are further reduced by subsequent rebates, fees and credits.” Ms. Waterer testified that: “In some instances, if we had a direct purchasing contract, a direct warehousing contract customer, there may have been performance incentive rebates that would have been, depending on their performance, within the terms of whatever [the] contract stipulation was. There may have been rebates that they got subsequent to that.” Pls.' Ex. E, 7/24/07 Waterer Dep. at 791:16-792:1.

Plaintiffs' Reply to Statement #13:

It is undisputed that most Roxane multisource customers have contracts with Roxane. Roxane cannot seriously dispute that customers with contracts buy Roxane drugs at contract prices. As Roxane reproduces above, its 30(b)(6) corporate designee testified that “if there was a contract on an individual product, it would have sold at the contract price.” The parties agree that contract prices are below WAC. The remainder of Roxane's response is irrelevant, disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

14. Roxane also enters into contracts with wholesalers. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 48:21-49:17; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 554:18-555:19; 558:15-559:23; 570:8-572:12. Some wholesaler contracts provide for product-specific pricing and incentives. See Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 585:18-590:10; Waterer Deposition Exhibit 72 (Exhibit D); 616:22-619:24. Product specific pricing is below WAC. See Waterer 5/9/07 30(b)(6) Dep. (Exhibit B) at 616:22-619:24. Product specific incentives (rebates/fees/allowances) reduce wholesaler's acquisition cost for the relevant Roxane product. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 88:5-16; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 788:17-792:1.

Roxane's Response to Statement No. 14: Roxane acknowledges that it enters into contracts with some wholesalers. With respect to the second sentence of Alleged Fact No. 14, Roxane disputes that “[s]ome wholesaler contracts provide for product-specific pricing and incentives.” This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5. n.1. Ms. Waterer testified that contracts with wholesalers were categorized based on the wholesalers’ level of compliance with the contract, and “depending on the level of compliance that the category demanded, they would get increasingly preferential pricing.” Pls.’ Ex. D, 5/11/07 Waterer Dep. at 588:2-8, 588:14-590:9. Ms. Waterer also testified that wholesaler contracts typically include a “prompt-payment discount,” and “sometimes, at the launch of a product, [Roxane] may offer a discount.” Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:2-13. A discount offered at launch is “[g]enerally in recognition of the fact that [wholesalers are] going to have to update all of their systems and find new shelf space and rearrange their inventory[.]” Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:16-21.

With respect to the third sentence of Alleged Fact No. 14, Roxane disputes that “[p]roduct specific pricing is below WAC.” This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. The portion of the record cited contains Ms. Waterer’s discussion of the prompt-payment and launch discounts. Pls.’ Ex. D, 5/11/07 Waterer Dep. 617:2-21. And with respect to both the third and fourth sentences, the definition of WAC is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price....*” 42 U.S.C. § 139w-3a(c)(6)(B) (2005). Thus, by definition, the WAC is likely to be higher than a wholesaler’s net price for Roxane products, because it is exclusive of “prompt pay or other discounts, rebates or reductions, price.”

Plaintiffs’ Reply to Statement #14:

It is undisputed that Roxane enters into contracts with wholesalers. The parties agree that some of Roxane’s wholesaler contracts include preferential pricing which depends on their level of compliance. *See* Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 554:18-555:19; 558:15-559:23; 570:8-572:12. The parties furthermore agree that wholesaler contracts with Roxane typically include a prompt pay discount, and sometimes at product launch another discount. Roxane cannot reasonably dispute that these discounts lower the wholesaler’s price for Roxane multisource products below the WAC in every instance where any of them apply. *See* Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 88:5-16; Roxane 30(b)(6) (Waterer) 7/24/07 Dep. (Exhibit E) at 788:17-792:1. The remainder of Roxane’s response is irrelevant and disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

15. Roxane's definition of AWP was merely "functional" in the sense that for generic products, Roxane sets AWP at 10% below the competing brand product, and didn't "think about" it anymore. In other words, AWP, once set for a Roxane generic product, remains the same regardless of changes in actual market prices. *See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 69:1-14.*

Roxane's Response to Statement No. 15: Roxane acknowledges that AWP is a "functional term [that] is most commonly at launch tied to a brand's AWP." Pls.' Ex. B, 5/9/07 Waterer Dep. at 69:17-23. Ms. Waterer testified that "[i]t is most commonly set at 10 percent below the brand's AWP when a product launches. And for the most part, that's about as much as we think about AWP." Pls.' Ex. B, 5/9/07 Waterer Dep. at 69:17-23. With respect to the second sentence, Roxane disputes that "AWP, once set for a Roxane generic product, remains the same regardless of changes in actual market prices." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane understood that industry practice for generic products was that, after launch, the AWP typically was not changed. Ex. A, 12/12/08 Waterer Dep. at 94:17-95:5. Two exceptions to this rule are: (1) when a Roxane drug becomes a sole-source drug, Roxane may increase all of its prices across the board, including the AWP; and (2) when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. Ex. B, 5/9/07 Waterer Dep. at 74:11-76:7.

In any event, Alleged Fact No. 15 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

Plaintiff's Reply to Statement #15:

Roxane admits that its definition of AWP was merely "functional" in the sense that for generic products, Roxane sets AWP at 10% below the competing brand product, and didn't "think about" it anymore. The parties agree that AWP, once set for a Roxane generic product, remains the same regardless of changes in actual market prices, unless a Roxane drug becomes a sole-source drug, when Roxane may increase all of its prices across the board, or when a customer complains and points out that Roxane's AWP is significantly lower than its competition. Responding further, plaintiffs incorporate their reply to Statement #6 herein. The remainder of Roxane's response is irrelevant and disputed. No further reply is required.

16. Roxane enters into contracts with other relevant Pharmacy Providers ("Non-retail PPs"). See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 48:21-50:25; Roxane 30(b)(6) (Waterer) 5/11/07 Dep. (Exhibit D) at 584:2-585:11. Some non-retail PP contracts provide for baseline rebates. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 87:1-88:4. Baseline rebates reduce non-retail PPs' acquisition cost for all Roxane products. See Roxane 30(b)(6) (Waterer) 5/9/07 Dep. (Exhibit B) at 87:1-88:4.

Roxane's Response to Statement No. 16: Roxane disputes that "Roxane enters into contracts with other relevant Pharmacy Providers." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that Roxane enters contracts with "warehousing chains" and "buying groups," which are "conglomeration[s] of multiple pharmacies that have agreed to participate within the buying group." Pls.' Ex. B, 5/9/07 Waterer Dep. at 49:6-24. Ms. Waterer also testified that Roxane may contract with "mail-order purchasers" and "long-term care, staff model HMO[s]." Pls.' Ex. D, 5/11/07 Waterer Dep. at 584:7-15.

With respect to the second and third sentences of Alleged Fact No. 16, Roxane disputes that any of its contracts provide for "baseline rebates." This alleged fact is not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. Ms. Waterer testified that some contracts were categorized based on the level of compliance with the contract, and "depending on the level of compliance that the category demanded, they would get increasingly preferential pricing." Pls.' Ex., D, 5/11/07 Waterer Dep. at 588:2-8; 588:14-590:9. Ms. Waterer also testified that contracts typically include a "prompt-payment discount," and "sometimes, at the launch of a product, [Roxane] may offer a discount." Pls.' Ex. D, 5/11/07 Waterer Dep. 617:2-13.

And, as previously discussed in Roxane's Response to Alleged Fact No. 14, the very definition of WAC is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price....*" 42 U.S.C. § 139w-3a(c)(6)(B) (2005). Thus, by definition, an "acquisition cost" is exclusive of "prompt pay or other discounts, rebates or reductions in price."

Plaintiffs' Reply to Statement #16:

The parties agree that Roxane enters into contracts with chain pharmacies, pharmacy buying groups, mail-order pharmacies, and long-term care staff model HMOs. The parties also agree that these contract customers receive certain discounts, including performance-based discounts, product launch discounts, and prompt pay discounts. The remainder of Roxane's response is irrelevant and disputed and constitutes argument improper in a 56.1 statement. No further reply is necessary.

17. Roxane's reported prices are inconsistent with the definition of reported prices in the OIG 2003 Compliance Guidelines. See Boehringer Ingelheim Roxane, Inc. 30(b)(6) (Judy Waterer) 12/12/08 Deposition Transcript (Exhibit F) at 149:17-155:8 (hereinafter, "Roxane 30(b)(6) (Waterer) 12/12/08 Dep. (Exhibit F)") (interpreting the OIG Guidelines to say simply that the reported prices must be what they are represented to be, and because Roxane used the industry definition of AWP (which bears no relation to actual prices generally and currently available) Roxane must therefore be in compliance); Deposition of Thomas Russillo dated 1/8/09 ("Exhibit G") at 239:11-242:8 (Roxane was aware of the OIG Guidelines, but did not consider them in approving prices for publication at any time thereafter).

Roxane's Response to Statement No. 17: Roxane disputes that "Roxane's reported prices are inconsistent with the definition of reported prices in the OIG 2003 Compliance Guidelines," and Roxane disputes Plaintiffs' characterization of Ms. Waterer's cited testimony. These alleged facts are not facts, but rather are arguments and mischaracterizations that are not properly supported by the evidence in the record. *O'Brien*, 440 F. Supp. 2d at 5 n.1. In response to being read "a paragraph entitled integrity of data used to establish or determine government reimbursement," Ms. Waterer responded, "I don't recall specifically reading that, but I would think that we would have a responsibility to report pricing that was correct." Pls.' Ex. F, 12/12/08 Waterer Dep. at 150:1-151:3. Ms. Waterer went on to testify, "I don't specifically recall hearing anything in that [paragraph] that defined that the government believed that AWP was anything other than what the industry understood it to be." Pls.' Ex. F, 12/12/08 Waterer Dep. at 151:11-14.

And nobody in the industry thought that AWPs bore a predictable relationship to market prices for drugs. Ex. A, 12/12/08 Waterer Dep. at 26:7-28:1 ("[W]e've never heard [AWP] described as anything else. In many, many, many years in the industry, [AWP] has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated average of prices in the marketplace."). In fact, "the government would have every reason to know that [AWP] was not defined in the industry or in any general practice as some kind of actual average of wholesale prices." Ex. A, 12/12/08 Waterer Dep. at 138:14-139:11. This is because "[i]t would be irrational to think that anybody doing that reimbursement would think that that's the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was." Ex. A, 12/12/08 Waterer Dep. at 29:9-14.

Roxane also disputes Plaintiffs' characterization of Mr. Russillo's testimony. Mr. Russillo was asked if "Roxane considere[d] the OIG guidance with respect to AWP in the formulation of any Roxane pricing practices," and Mr. Russillo responded, "[I]f there was any consideration made, and I don't recall at the time what we were doing, but we would have certainly taken that into account." Pls.' Ex. G, 1/8/09 Russillo Dep. at 241:1-10. Mr. Russillo went on to testify, "I'm sure that we had legal review of the guidance. And if there was anything that needed to be changed, we were told. But I don't recall being told to change anything." Pls.' Ex. G, 1/8/09 Russillo Dep. at 242:5-8.

In any event, Alleged Fact No. 17 is immaterial to Plaintiffs' motion because, as set forth in General Response No. 1, CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt. at ¶ 34.

Plaintiffs' Reply to Statement #17:

The parties agree that Roxane had a duty to report prices that were correct. The remainder of Roxane's response is irrelevant and disputed and constitutes argument improper in a 56.1 statement. No further reply is required.

Dated: July 3, 2009

Respectfully submitted,

**City of New York and New York Counties in
MDL 1456 except Nassau and Orange by**

KIRBY McINERNEY, LLP
825 Third Avenue
New York, New York 10022
(212) 371-6600

/s/ Joanne M. Cicala

By: Joanne M. Cicala
James P. Carroll Jr.
Jocelyn R. Normand
Kathryn B. Allen

Ross B. Brooks, Esq.
MILBERG LLP
One Pennsylvania Plaza
New York, NY 10119
(212) 594-5300
Special Counsel for the County of Nassau

Theresa A. Vitello, Esq.
LEVY PHILLIPS &
KONIGSBERG, LLP
800 Third Avenue
New York, NY 10022
(212) 605-6205
Counsel for the County of Orange

CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: July 3, 2009

/s/
James P. Carroll, Jr.
Kirby McInerney LLP
825 Third Avenue, 16th Floor
New York, NY 10022
(212) 371-6600